WEEK ENDING MAY 3, 2013

OPP Weekly Activity Report

Highlights Include:

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FIELD & EXTERNAL AFFAIRS DIVISION

Report on Honey Bee Health. On Thursday May 2, EPA and USDA released a comprehensive scientific report on honey bee health. The report states that there are multiple factors playing a role in honey bee colony declines, including parasites and disease, genetics, poor nutrition and pesticide exposure. The report outlines multiple policy actions and research questions to be considered surrounding honey bee health. Acting Administrator Bob Perciasepe, Acting Assistant Administrator Jim Jones and Office Director Steven Bradbury joined Sonny Ramaswamy, Administrator of USDA's National Institute of Food and Agriculture, and top scientists to host conference calls to discuss the new report on the factors contributing to decline in honey bee health in the United States. The report summarizes the latest science and emerging research on honey bee health, as discussed at The National Stakeholder Conference on Honey Bee Health in October 2012. (Anne Overstreet, 308-8068) (News Release can be found at: http://yosemite.epa.gov/opa/admpress.nsf/d0cf6618525a9efb85257359003fb69d/e04602a5e7aa060685257b5f004a12d3!OpenDocument

OPP Hosts Indonesian Delegation. On May 1, a three-member delegation from the Indonesian National Agency for Drug and Food Control, visiting the United States as part of the Department of State's International Visitor Leadership Program, visited OPP. Arranged by the Meridian International Center, the program seeks to impart knowledge and information about a safer food supply, public policy and food safety issues; provide a clear and concise understanding of the U.S. and international food safety systems; offer tools to improve regulatory transparency, eliminate trade barriers between U.S. exporters and Indonesian importers, and explore options for mutually beneficial trade; and examine science-based methods employed by U.S. regulatory institutions to ensure food safety. OPP/FEAD was the first stop in a multi-agency, 2-week program. General presentations on Human Health Risk Assessment and Risk Management were provided by Michael Metzger of HED and Diane Isbell of RD. (Ron Kendall 305-5561)

ICR Kick-Off Meeting. FEAD hosted its annual ICR Kick-Off meeting this week, inviting representatives of all the OPP divisions that will participate in ICR renewals over the next year. Registration Fees, 1080 Collars, DCIs, Child-Resistant Packaging, PIPs, 6(a)2 and EUP applications are up for renewal this year. The ICR teams are led by FEAD, supported by BEAD and include divisions that rely on the information collected. (Martha Shimkin, 305-5160)

PESTICIDE RE-EVALUATION DIVISION

EPA Requests Comment on NMFS' Draft Measures to Protect Threatened and Endangered Pacific Salmon. As announced on Thursday, May 2, EPA is requesting

comment by May 31, 2013, on draft Reasonable and Prudent Alternatives (RPAs) proposed by the National Marine Fisheries Service (NMFS) in their May 1, 2013, draft Biological Opinion for diflubenzuron, fenbutatin-oxide, and propargite. The draft Biological Opinion addresses the potential effects from these pesticides to Pacific salmon and steelhead listed as endangered or threatened under the Endangered Species Act. Comment from interested parties will help EPA determine whether the alternatives can be reasonably implemented or if other measures may provide adequate protection but result in less impact to pesticide users. The agency will forward all comments received to NMFS for their consideration. NMFS has a legal obligation to issue the final Biological Opinion by June 30, 2013. The draft Biological Opinion is available in docket EPA-HQ-OPP-2008-0654 at Regulations.gov. On April 17, 2013, OPP met with representatives of NMFS to discuss the draft Biological Opinion and proposed RPAs for diflubenzuron, fenbutatin-oxide, and propargite. The meeting was held to allow PRD and EFED to provide additional feedback prior to the May 2 release of the draft opinion for public comment. (Catherine Eiden, ESA, 703-305-7887; Steven Snyderman (diflubenzuron), 703-347-0249; Ricardo Jones (fenbutatin-oxide), 703-347-0493; Wilhelmena Livingston (propargite), 703-308-8025)

Follow-up to Council for the Conservation of Migratory Birds (Council) Meeting. Council staff met on Thursday, May 2, to discuss action items identified at the most recent Council meeting. Council staff is developing a new process for production of the Council report; the report is intended to highlight the progress of federal agencies' efforts to protect migratory birds as they administer their programs. Staff also considered new formats for and timing on delivering the annual survey to federal agencies intended to track their progress implementing migratory bird conservation measures. Council staff represents more than a dozen federal agencies working toward the conservation of migratory birds. (Melissa Panger (EFED), 703-305-6136; Cathy Eiden (PRD), 703-305-7887)

Chlorethoxyfos Meeting with Registrant. On May 2, 2013, members of EFED and PRD met with representatives from Amvac Chemical Corporation, Compliance Services International, and Huntingdon Life Sciences, to discuss preliminary findings of an aquatic aerobic metabolism study required for the registration review of chlorethoxyfos. EFED will review the information presented and will respond with written guidance for Amvac. Chlorethoxyfos is an organophosphate insecticide registered for use on corn to control corn rootworms, wireworms, cutworms, seed corn maggots, white grubs and symphylans. The registration review docket for chlorethoxyfos (EPA-HQ-OPP-2008-0843) opened in December 2008. (Kelly Ballard, 703-305-8126)

OPP Meets with Joint Glyphosate Task Force. On April 30, 2013, staff from BEAD, EFED, HED, PRD and RD met with representatives from the Joint Glyphosate Task Force (JGTF) to discuss their continuous efforts to tabulate use rates for glyphosate

products, as well as the status of registration review and the projected schedule. The JGTF has focused on a subset of crops and is attempting to identify particular application parameters (*e.g*. application rates or number of applications) that are currently missing from glyphosate labels. The absence of application parameters may present difficulties for product users, and presents difficulties for the agency when it conducts its risk assessment. The parties discussed how all glyphosate use parameters may be captured in a single document that may be considered a "master glyphosate label." The glyphosate documents can be found in docket EPA-HQ-OPP-2009-0361. (Carissa Cyran, 703-347-8781)

Propylene Oxide (PPO) Focus and RD Amendment Action Meeting. On May 2, 2013, the Registration Division and PRD hosted the PPO registrants and industry representatives to discuss the HED Technical Screen for EPA reg# 47870-3 (Amendment Action to Revise Buffer Zones), followed by a Focus meeting to discuss the upcoming Registration Review of PPO. EPA provided the registrants with several questions on the details of PPO use sites, application, emissions, monitoring and exposure, and other uncertainties. Use data that would be helpful for the risk assessments and the registration review schedule were also discussed; the docket will open in September 2013. The registrant will follow up with any additional information not provided in the meeting. (Garland Waleko (PRD), 703-308-8049; Heather Garvie (RD), 703-308-0034)

BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

MLB Completes Practice Session 5 on the Rapid Viability Polymerase Chain Reaction (RV-PCR). A partnership is in place between the Office of Emergency Management (OEM) and the Office of Pesticide Programs (OPP) to develop EPA's anthrax analytical capability and preparedness in case of a wide-area anthrax event. OPP and OEM agreed to have monthly practice session (for six months) to remain proficient in the RV-PCR method. Practice session 5 was conducted by two teams independently the week of April 22nd. In an this practice session, the team members were switched, the spores were incubate for no more than 9 hrs, and the extracted DNA was heated in a more conservative manner. Both teams had the appropriate response (positive and negative outcomes came out as expected) in session 5. The data were tabulated and shared with OEM. For practice session number 6, OPP will propose that each analyst will run unknown samples independently following the RV-PCR method. (Jafrul Hasan, 410-305-2657; Jason Duncan, 410-305-2619)

Scientists Complete Laboratory Testing for Second Collaborative Study of the OECD Method. In conjunction with seven other laboratories, MLB launched a collaborative study of the OECD test method with *Mycobacterium terrae* in March. The OECD test method was intended to be an international harmonized

test method for evaluating the efficacy of disinfectants. In this collaborative study, each laboratory is evaluating a reference standard at two levels of presumed efficacy and four EPA-registered hospital disinfectants against *M. terrae* in a blinded, randomized and replicated fashion. MLB has completed the testing phase of the collaborative study including all three replicates of the reference standard and method performance assays in addition to a neutralization assay. Due to the slow growing nature of the organism, the data will be collected over the next three weeks. (Knoxley Japal, 410-305-2660; Rebecca Pines, 410-305-2635)

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

Protective Rodenticide Bait Station Products - The ITRMD Web Team worked with Carol Stangel (PRD) to update the Protective Rodenticide Bait Station Products on the Pesticide Reregistration website. While EPA has approved all the protective products listed, pesticide producers decide how to market their products. For example, the D-Con products on this list are not being sold at present. For more information, please visit the web page at http://www.epa.gov/pesticides/mice-and-rats/rodent-bait-station.html (Mario Steadman, 305-8338)

OPP FOIA Request Status Report – April 22- 26, 2013

Requests Received		*Requests Closed*			*Requests Open*		
FY13	***This Week***	***FY13***	***FYTD***	***This Week***	***FY13***	***Prior Years***	***Total***
276	12	145	227	6	131	134	265

(Ana Espinoza, 703-347-0102)

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

Public Participation Comment Period Opens for New Biochemical Plant Growth Regulator. On May 2, BPPD opened a 15-day public comment period for Complex Polymeric Polyhydroxy Acids (CPPA), a new biochemical active ingredient intended for use as a plant growth regulator (PGR). The proposed end-use product is intended for use on field and greenhouse crops, fruits, nuts, vines and ornamentals. CPPA is derived from naturally occurring organic matter (NOM) in soils and ground and surface waters. Documents supporting this action, including proposed product labels, are available for comment in docket EPA-HQ-OPP-2009-0917 until May 17, 2013. (Menyon Adams, 347-8496)

BPPD Presents at China - U.S.A Workshop on Microbial Safety Assessment. From April 14 – 19, BPPD's Gail Tomimatsu and Ibrahim Barsoum attended the China-USA Workshop on Microbial Safety Assessment in Nanjing, China. Gail and Ibrahim were invited by the Nanjing Institute of Environmental Sciences - Ministry of Environmental Protection to give presentations on the registration and regulation of microbial pesticides in the U.S. They each presented on topics including ecological risk assessment, data requirements, and registration processes. Gail and Ibrahim also visited local environmental science labs. The workshop was successful and a recommendation was made for future cooperation between U.S. and China environmental scientists. (Gail Tomimatsu, 308-8543; Ibrahim Barsoum, 308-6417)

BPPD Attends U.S.-China Biotechnology Working Group Meetings. On April 22 and 23, a delegation from Beijing, China met with representatives from USDA-APHIS-BRS, USDA-FAS, BPPD, FDA-CFSAN, and FDA-CVM at USDA facilities in Washington, D.C. The meetings were intended to continue dialogue on regulation and new product development of agricultural biotechnology. Trade-related issues were key to the discussions, as possible low level presence (LLP) of unapproved products containing pesticidal traits in the absence of a tolerance or tolerance exemption is a potential trade disrupting factor. In addition, negotiations are underway to encourage approval of biotech products in the U.S. and China in such a manner as to be less asynchronous. This could possibly minimize possible trade disruptions associated with LLP, as U.S. commodities including soy and maize are heavily traded with China. Additionally, the Chinese delegation and FDA-CVM representatives each presented an overview of intended regulation for animal biotechnology products, as did U.S. representatives from FDA-CVM. (Keith Matthews, 308-8128; John Kough, 308-8267; Chris Wozniak, 308-4043)

ENVIRONMENTAL FATE & EFFECTS DIVISION

Teleconference with Health Canada's Pest Management Regulatory Agency and Crop Life Canada. On April 29, 2013, representatives of EFED and PRD participated in a teleconference with Health Canada's Pest Management Regulatory Agency (PMRA) and representatives of Crop Life Canada. The meeting focused on six themes: the PMRA evaluation of bee kill incidents in 2012, best management practices (BMPs) to reduce spray drift, a pollen/nectar residue database project, the PMRA response to comments from the FIFRA Scientific Advisory Panel (SAP) on the risk assessment framework for bees, activities in Europe regarding the regulation of neonicotinoid insecticides, and label language. PMRA has been working with EPA and the California Department of Pesticide Regulation to develop a quantitative risk assessment process for bees and this process will be used as a basis for identifying and mitigating potential risks through appropriate label language and BMPs. PMRA has also been working

closely with EPA on the Registration Review of the neonicotinoid insecticides. (Tom Steeger, 703-305-5444; Tom Moriarty, 703-305-5035).

Meeting of the Honey Bee Colony Collapse Disorder (CCD) Steering Committee. On April 29, 2013, EFED staff participated in a meeting of the Honey Bee Health and Colony Collapse Disorder (CCD) Steering Committee, formerly known as the CCD Steering Committee. Participants also included representatives from USDA's Office of Pest Management Policy (OPMP), Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), National Institute of Food and Agriculture (NIFA), the Natural Resources Conservation Service (NRCS), and the National Agricultural Statistics Service (NASS). Participants discussed the revision of the CCD Action Plan that was initially drafted in 2007. The revised Action Plan will be based on input provided through the National Stakeholder Conference on Pollinator Health that was held in October 2012, the proceedings of which were recently released. The revised Action Plan will identify knowledge gaps and the goals, priorities, and future actions to address these knowledge gaps. Members of the Steering Committee who served as breakout session facilitators at the National Stakeholder Conference will serve as leads in developing their respective sections of the revised Action Plan. (Tom Steeger, 703-305-5444).

HEALTH EFFECTS DIVISION

Meeting With MBIP On Use Commodity Fumigation Survey and Use In Risk Assessment: Staff from several divisions participated in a meeting (5/2/13) with the Methyl Bromide Industry Panel (MBIP) focused on a survey conducted in the commodity fumigation industry detailing use practices associated with methyl bromide. MBIP indicated the survey was completed by users who account for approximately 95 percent of its use. The information was collected to see if additional analyses could be completed using PERFUM to better represent some existing industry practices. In general, the survey results indicate that the analyses in the risk assessment are complete. MBIP did identify, however, some additional PERFUM analyses that are needed to account for situations not currently included in the Agency assessment (e.g., some facilities use larger aeration fans, faster exit air velocities, different vent diameters). A strategy was also discussed for how this additional information would be submitted and timing relative to Agency goals for completing this action. (Jeff Dawson, 305-7329)

Regulatory Co-Operation Council (RCC) Consideration of MRL Differences: HED (D.Vogel, D. Miller, B. Sarkar, S. Funk) and RD (L. Rossi, J. Herndon) met via teleconference with PMRA (P. Chan, M.Thomas, et. al.) to discuss some differences in Canadian and US MRLs for several active ingredients. The importance of doing coordinated reviews and looking at all the data were emphasized. The situation of MRL estimation with only 2 trial values was also

discussed, including the US proposal to use 5 X mean as the best estimate. It was agreed that this may not be appropriate for postharvest uses and greenhouse uses, where the variation in results is small compared to field trials. Additional analysis will be done to determine the best path forward for post-harvest and greenhouse uses with limited trials. (Steve Funk, 305-5430)

ANTIMICROBIALS DIVISION

Antimicrobial Registration Review DCIs Issued. On April 25, 2013, the Antimicrobials Division issued the Glycolic acid and salts data call-ins (GDCI-000101-1065) to support the upcoming registration review risk assessment. In the near future, a redacted (i.e., non-company specific) copy of the DCI mail-out package will be posted to the registration review docket (EPA-HQ-OPP-2011-0422) at www.regulations.gov. (Seiichi Murasaki, 703-347-0163)

REGISTRATION DIVISION

Notice of Receipt Published for the Section 18 Use of Ethylene Oxide On April 26, 2013, the *Federal Register* published a Notice of Receipt announcing receipt of an application from the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) requesting a Section 18 quarantine exemption for the use of ethylene oxide to sterilize enclosed animal isolator units in USDA laboratories. This is the third quarantine exemption request by USDA for this use. The applicant is proposing use of an active ingredient which is the subject of a Special Review. The comment period ends on May 13, 2013. (Keri Grinstead, 703/308-8373)

Registration Actions Granted Under FIFRA Section 18 Emergency Exemptions					
State/Federal Agency	**Chemical Emergency Exemption Number**	**Product Name EPA Reg/ File Symbol**	**Crop/Site**	**Pest**	**Authorization Date**
Specific Exemption(s):					
Louisiana	Fluxapyroxad 13-LA-05	Sercadis (7969-309)	Rice	Sheath Blight	05-01-2013
					Debra Rate, 703/306-0309
Alabama	Hop Beta Acids 13-AL-02	HopGuard (Unregistered)	Beehives	Varroa Mite	05-01-2013
Oklahoma	Hop Beta Acids 13-OK-01	HopGuard (Unregistered)	Beehives	Varroa Mite	05-01-2013
					Stacey Milan Groce, 703/305-2505

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	**Company**	**Registration Number**	**Action Code***	**Due Date**	**Response Date**
The Fungicide Branch granted:					
Metalaxyl	Albaugh Inc.	42750-250	R301	7/22/2013	5/1/2013
				Robert Westin, 703/305-5721	
The Herbicide Branch granted:					
Glyphosate	Repar-Glypho, LLC	86004-1	R340	6/14/2013	4/30/2013
				Juanita Gilchrist, 703/305- 6965	
Clethodim	Albaugh	42750-244	R310	5/6/2013	4/29/2013
				Dianne Morgan, 703/ 305-6217	
Fluridone	Sepro Corporation	67690-61	R300	5/16/2013	4/29/2013
				Grant Rowland, 703/347-0254	
The Insecticide-Rodenticide Branch granted:					
Spirotetramat	Bayer CropScience LP	264-1049 264-1050 264-1065	R190	5/2/2013	5/2/2013
				Rita Kumar, 703/308-8291	

R190 – Additional food uses; 6 or more submitted in one application; **R300** – New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation or selective data citation where applicant owns all required data or submits specific authorization letter from data owner. Category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission or data matrix; **R301** – New product identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner; **R310** – New end-use or manufacturing use product; requires review of data package within RD; includes reviews and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy; and **R340** – Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient) (2)